UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

PFIZER INC., Plaintiff, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL, and CHRISTI A. GRIMM, in her official capacity as Acting Inspector General in the Office of Inspector General for the U.S. Department of Health and Human Services, Defendants.	Case No. 1:20-cv-4920-MKV

BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF PLAINTIFF PFIZER INC.'S OPPOSITION TO DEFENDANTS' CROSS-MOTION TO DISMISS THE COMPLAINT

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INTRODUCTION AND INTEREST OF AMICUS CURIAE

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, non-profit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's members are dedicated to discovering medicines that help patients lead longer, healthier, and more productive lives. PhRMA frequently files amicus curiae briefs in cases raising matters of significance to its members.

PhRMA's members are committed to compliance with provisions of federal law, including the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), and they devote significant resources to preventing fraud and abuse. In that spirit, PhRMA has a substantial interest in ensuring that the legal standards governing the pharmaceutical industry are stable, predictable, and consistent with sound public policy. The Office of the Inspector General of the U.S. Department of Health and Human Services ("OIG") plays an important role in providing the industry with needed guidance on the scope of companies' obligations under federal law; the AKS provides that OIG "shall issue advisory opinions" as to "[w]hether any activity or proposed activity constitutes grounds for the imposition of a sanction" under that statute. 42 U.S.C. § 1320a-7d(b)(2)(E); *see also* 42 C.F.R. § 1008.5. PhRMA members may avail themselves of this statutorily-created process to seek opinions from OIG as to whether an arrangement or a proposed arrangement constitutes prohibited remuneration under the AKS. OIG's advisory opinion process can be used to provide clarity regarding the legal boundaries within which manufacturers must operate, and PhRMA and its members greatly appreciate the efforts that OIG and its staff devote to developing guidance under this process.

From time to time, OIG provides guidance to requestors such as PhRMA members that exposes the requestor to civil and criminal enforcement risk if the requestor proceeds with a given course of action, whether by explicitly guiding against a proposed course of conduct or by

providing a response to a request for guidance that leaves open the potential for enforcement. Under either of these circumstances, PhRMA members need access to the federal courts on a timely basis, so that they may gain a definitive ruling as to the legality of a proposed program before they risk the severe penalties of criminal sanctions and exclusion from federal health care programs. That need is all the more acute for parties that risk liability under the AKS, given the due process concerns that are created when regulated entities are left to guess as to their obligations under such a broadly and generally worded criminal statute.

Under settled principles of justiciability, a regulated party need not run that sort of a risk in order to gain such a ruling. It is enough for the party to show that it faces a credible threat of enforcement against it should it proceed with the course of conduct it hopes to undertake. And under these black-letter principles of law, Pfizer has presented a dispute that is ripe for this Court's resolution. In 2019, Pfizer received Food and Drug Administration ("FDA") approval for two medications for the treatment of a rare heart valve condition, transthyretin amyloid cardiomyopathy ("ATTR-CM"). Currently, these medications are the only approved pharmaceutical treatments for ATTR-CM. In order to assist Medicare beneficiaries unable to afford this groundbreaking medication, Pfizer developed two financial assistance programs that it hoped would increase access among a vulnerable patient population. Before implementing the programs, Pfizer requested that OIG issue advisory opinions stating whether the proposed programs ran afoul of the AKS. OIG declined to issue an opinion with regard to one proposed program, and reasoned in a published opinion that Pfizer's second proposed program could violate the AKS's prohibition against renumeration "to induce" the purchase of items paid for under federal health care programs, 42 U.S.C. § 1320a-7b(b)(2). Pfizer sought judicial review.

PhRMA does not seek to address the merits of Pfizer's dispute with OIG over the proper interpretation of the AKS. PhRMA agrees with Pfizer, however, that this case is appropriate for judicial review. A controversy is ripe for a court's review if it presents a dispute that is fit for judicial resolution, and if the plaintiff would suffer a hardship if judicial review were to be deferred. This case presents pure issues of law that are fit for this Court to address now. And PhRMA members would suffer a hardship if they were forced to wait for enforcement actions to be brought against them in order to learn how the judiciary would interpret the scope of the Anti-Kickback Statute. The public would suffer a hardship as well; unless manufacturers are able to gain guidance from the courts, they may be forced as a practical matter to refrain from pursuing programs that could be helpful to the public, such as the financial assistance programs for middle-income Medicare beneficiaries that are at issue in this case. OIG's responses to Pfizer's requests for guidance as to the legality of its proposed programs thus presents a dispute that is ripe for this Court's consideration, and this Court has jurisdiction to consider this case on the merits.

FACTUAL AND PROCEDURAL BACKGROUND

Pfizer offers two FDA-approved medications, Vyndaqel® (tafamidis meglumine) and Vyndamax® (tafamidis) (the "Medications") for the treatment of ATTR-CM, a rare condition affecting the heart muscle. Compl. ¶ 4. Pfizer has proposed two financial assistance programs to help Medicare beneficiaries afford these medications. The first would provide direct assistance to beneficiaries prescribed the Medications through a copay and coinsurance assistance program under which the beneficiary would be responsible for a monthly copayment, while Pfizer would pay the beneficiary's remaining cost-sharing obligations (the "Direct Assistance Program"). *Id.* ¶ 8. The second would provide indirect assistance through an independent charity, which would provide financial assistance to patients who have difficulty covering the costs of the Medications,

as well as any other prescription drugs used to the treat the symptoms of the disease (the "Indirect Assistance Program"). *Id.*

OIG's regulations permit a party to request an advisory opinion if it certifies that the information that it provides to the agency is true and correct, and that it in good faith intends to undertake the proposed arrangement that is described in the request. 42 C.F.R. § 1008.38. Pfizer followed this procedure to seek OIG's guidance on its two programs through advisory opinions, specifically asking OIG to opine on whether its proposed actions would run afoul of the AKS. Compl. ¶ 103. OIG declined to issue guidance on Pfizer's Indirect Assistance Program, stating that a similar financial assistance program was subject to an ongoing investigation or enforcement proceeding by another government agency. *Id.* It also alerted Pfizer in December 2019 that it had reached an unfavorable opinion on its Direct Assistance Program, a decision that it reiterated in May 2020. Compl. ¶¶ 105, 108. On September 18, 2020, OIG issued its advisory opinion, concluding in part that the Direct Assistance Program "would generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals for, or purchases of, items and services reimbursable by a Federal health care program were present …." OIG Advisory Opinion No. 20-05 at 2. OIG opined that "we believe there is a risk that the availability of the Subsidy Program could sway a physician to prescribe the Medications over any other treatment, even if such treatments are equally (or more) effective or have a lower overall cost." *Id.* at 23. However, OIG declined to reach "a definitive conclusion" regarding the existence of an anti-kickback statute violation. *Id.* at 27.

In June 2020, Pfizer filed suit in this Court, asking for, among other things, a declaration that its two proposed programs do not violate the AKS. Compl. ¶ 139. OIG has filed a cross-

motion to dismiss the complaint or for summary judgment, arguing in part that Pfizer's claims are not subject to judicial review. Dkt. No. 44.

ARGUMENT

OIG asserts that this dispute does not raise any issue that is ripe for the Court's consideration. This is incorrect; there is a live dispute between the parties as to the legality of Pfizer's proposed programs under the AKS and the constitutionality of governmental restrictions on those programs. Moreover, the time for a court to resolve a dispute like this one is now, rather than after a regulated party risks criminal sanctions and exclusion from federal health care programs in order to test OIG's views as to the breadth of the Anti-Kickback Statute. This case presents claims that are both constitutionally and prudentially ripe for this Court's consideration.

I. Pfizer's Claims Are Constitutionally Ripe.

The Declaratory Judgment Act provides that a district court, "[i]n a case of actual controversy within its jurisdiction, … may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). The Act permits courts to issue a declaratory judgment when "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (citing *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

Before granting a plaintiff's request for a declaratory judgment, the courts will consider whether the action presents a dispute that is both constitutionally and prudentially ripe for the Court's review. The constitutional ripeness inquiry turns, largely, on whether the plaintiff has Article III standing to bring the action. A plaintiff has standing—and, thus, presents a constitutionally ripe dispute—if its cause of action presents "a real, substantial controversy" in

which it has suffered "an injury in fact" that is, among other things, "actual or imminent." *Nat'l Org. for Marriage, Inc. v. Walsh*, 714 F.3d 682, 687 (2d Cir. 2013); *see also New York Civil Liberties Union v. Grandeau*, 528 F.3d 122, 130 n.8 (2d Cir. 2008) ("Standing and ripeness are closely related doctrines that overlap most notably in the shared requirement that the plaintiff's injury be imminent rather than conjectural or hypothetical.") (quotation marks and alterations omitted). The Second Circuit has noted there is a "low threshold" for a plaintiff to successfully plead an injury in fact, which "need not be capable of sustaining a valid cause of action, but may simply be the fear or anxiety of future harm." *Ross v. Bank of Am., N.A.(USA)*, 524 F.3d 217, 222 (2d Cir. 2008) (quotation marks omitted).

A plaintiff may show an injury in fact by demonstrating a credible threat that a statutory provision will be enforced against it. Under these circumstances, courts "do not require a plaintiff to expose himself to liability before bringing suit to challenge the basis for the threat." *MedImmune, Inc.*, 549 U.S. at 128-29; *see also Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) ("When an individual is subject to [threatened enforcement of a law], an actual arrest, prosecution, or other enforcement action is not a prerequisite to challenging the law."); *Berger v. Heckler*, 771 F.2d 1556, 1563 (2d Cir. 1985) ("One does not have to await the consummation of threatened injury to obtain preventive relief.") (quoting *Pennsylvania v. West Virginia*, 262 U.S. 553, 593 (1923)). For example, in cases raising constitutional claims, a plaintiff may demonstrate an injury for Article III purposes by showing "an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder." *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979). A credible threat of enforcement exists where the plaintiff's "fear of prosecution

[is] not imaginary or wholly speculative," *Driehaus*, 573 U.S. at 161, or "the threat of enforcement is not chimerical," *id.* at 164.

Pfizer has easily cleared the "low threshold," *Ross*, 524 F.3d at 222, to show that it suffers an injury in fact. It seeks to establish two alternative programs to provide middle-income Medicare beneficiaries with financial assistance to be able to afford its medications for the treatment of ATTR-CM. Pfizer has stated it is deterred from doing so without a ruling from this Court that it may legally proceed, in part out of fear that federal regulators would bring an enforcement action against it, and that regulators would consider the manner in which it speaks with an independent charity as evidence of a violation of the AKS. Pfizer's Mot. For S.J. at 8, 21-23 (Dkt. No. 34). Its intended course of conduct, then, is at least arguably affected with a constitutional interest. OIG is of the view that Pfizer's proposed programs are at least "arguably … proscribed by a statute," *Babbitt*, 442 U.S. at 298, as demonstrated by OIG's merits contentions in this lawsuit. And Pfizer has certainly shown that it faces a threat of enforcement that is far more than "imaginary," "speculative," or "chimerical," in light of its full course of dealing with federal regulators, including (1) the adverse advisory opinion that OIG issued with respect to Pfizer's proposed Direct Assistance Program; (2) OIG's representation to Pfizer that its Indirect Assistance Program programs is similar to programs pursued by other entities that are currently under investigation; and (3) Pfizer's corporate integrity agreement with federal regulators, which requires Pfizer to follow OIG's guidance so long as that guidance is lawful.[1]

OIG takes the position that its rejection of Pfizer's requests for favorable advisory opinions "is not, in itself, preventing Pfizer from doing anything it wishes to do." Mem. of Law in Opp'n to Pfizer's Mot. for S.J. and in Supp. of Defs.' Cross-Mot. to Dismiss the Compl. or for S.J. at 24

[1] *See* OIG, Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Pfizer Inc. (May 23, 2018), https://oig.hhs.gov/fraud/cia/agreements/Pfizer_Inc_05232018.pdf.

(Dkt. No. 45). This is not relevant to the ripeness inquiry. A regulated party does not need to demonstrate that it is literally impossible for it to proceed with its proposed programs in order to meet the Article III requirements of standing and constitutional ripeness. It is enough for it to show that it is put to the choice of risking an enforcement action if it so proceeds, or forgoing those programs altogether. "The dilemma posed by that coercion—putting the challenger to the choice between abandoning his rights or risking prosecution—is 'a dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate.'" *MedImmune*, 549 U.S. at 129 (citing *Abbott Labs. v. Gardner*, 387 U.S. at 152).

II. Pfizer's Claims Are Prudentially Ripe.

OIG contends that, even if the Court finds that it has Article III jurisdiction because the requirements of standing and constitutional ripeness are met, the Court should decline to exercise that jurisdiction by finding the case to be prudentially unripe. Mem. of Law in Opp'n to Pfizer's Mot. for S.J. and in Supp. of Defs.' Cross-Mot. to Dismiss the Compl. or for S.J. at 25-28 (Dkt. No. 45). As a general matter, "[t]o determine whether to abstain from a case on prudential ripeness grounds, [the court] proceed[s] with a two-step inquiry, requiring [it] to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Nat'l Org. for Marriage*, 714 F.3d at 691; *see also Sharkey v. Quarantillo*, 541 F.3d 75, 89 (2d Cir. 2008). The factors governing prudential ripeness weigh in favor of this Court considering the action on the merits.

As the Supreme Court noted in its most recent decision addressing the prudential ripeness doctrine, the notion that a federal court may decline to hear a case "on grounds that are 'prudential,' rather than constitutional … is in some tension with our recent reaffirmation of the principle that 'a federal court's obligation to hear and decide' cases within its jurisdiction 'is virtually unflagging.'" *Driehaus*, 573 U.S. at 167 (quoting *Lexmark Int'l, Inc. v. Static Control*

Components, Inc., 572 U.S. 118, 125-26 (2014) (internal alterations and quotation marks omitted)). The Court did not "resolve the continuing vitality of the prudential ripeness doctrine" in *Driehaus*, because the elements of fitness and hardship were "easily met" in that case. *Id.* But given the doubts that the Supreme Court has raised, "a court must proceed cautiously" before dismissing an action on the ground that it is prudentially unripe. *Vullo v. Office of Comptroller of Currency*, 378 F. Supp. 3d 271, 283 (S.D.N.Y. 2019); *see also id.* at 288 ("the Court would have to find overwhelming prudential considerations to decline jurisdiction on such grounds").

All of the prudential considerations weigh in favor of this Court fulfilling its virtually unflagging obligation to exercise its jurisdiction to decide this case. First, the issues that are raised in this case are fit for this Court's consideration. Pfizer contends that its proposed programs do not violate the AKS because the statute restricts only remuneration paid to corrupt a recipient's judgment as to the purchase of medical services; OIG contends, in turn, that no showing of a corrupt intent is needed. Pfizer contends that the threat of AKS enforcement against its Indirect Assistance Program violates the First Amendment by regulating the content of speech between Pfizer and independent charities; OIG disputes that the AKS raises First Amendment concerns. Pfizer contends that enforcement action against its patient assistance programs would violate the equal protection component of the Due Process Clause by effectively barring access to Medicare benefits on the basis of income; OIG disputes the existence of any equal protection violation. These are purely legal issues, and no further factual record needs to be developed for this Court's review. *See Citizens United v. Schneiderman*, 882 F.3d 374, 388 (2d Cir. 2018). "What future contingencies remain are not determinative of the questions before" this Court. *Nat'l Org. for Marriage*, 714 F.3d at 691.

In addition, the industry would face a hardship if this Court were to withhold its review, but OIG would face none. PhRMA members can risk criminal sanctions under the AKS and exclusion from federal health care programs if they proceed with patient assistance programs without a definitive judicial ruling as to the legality of those programs. This easily satisfies the hardship element under the prudential ripeness doctrine. *See Citizens United*, 882 F.3d at 388–89 (parties face hardship if they would be "require[d] … to risk losing their permission to [operate] before litigating this issue"); *see also Grandeau*, 528 F.3d at 134 (the "direct and immediate dilemma" of being forced to risk a violation of the law in order to gain judicial review demonstrates hardship). Moreover, it is not the industry alone that would suffer this hardship. If Pfizer is correct on the merits in this case, then the patients for whom it seeks to provide assistance—the middle-income Medicare beneficiaries who need its medications to treat ATTR-CM—would be deprived of a lawful means to gain access to useful treatments that they would otherwise be unable to afford. This Court's review is needed, and is needed now, to ensure that patients do not lose access to needed medications because industry members are deterred from offering assistance programs out of a reasonable concern that in doing so they would violate the AKS.

A finding of prudential ripeness is all the more warranted in a case, like this one, that touches on constitutional considerations. As noted, this case involves claims on the merits that restrictions on its patient assistance programs violate the First Amendment and the equal protection component of the Fifth Amendment's Due Process Clause. The posture of this case raises an additional issue of due process. Because the AKS is a criminal law, due process demands that the government put would-be defendants on clear notice of what conduct would violate the AKS. *See, e.g.*, *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 287 (D.C. Cir. 2015) (observing, in the context of the False Claims Act, "the potential due process problems posed by penalizing a

private party for violating a rule without first providing adequate notice of the substance of the rule") (internal citation and quotation omitted). Congress granted OIG the power to issue advisory opinions in part to provide such clarity. In its report on the proposed Health Coverage Availability and Affordability Act of 1996, the Committee on Ways and Means noted the following:

> Providers want to comply with the fraud and abuse statute, but many are unsure of how the statute affects them. These providers should be able to receive guidance from the government regarding financial arrangements. Little or no guidance is currently provided because there are no regulations and only insufficient safe harbors. Without this ability, a chilling effect is placed on legitimate arrangements, particularly when providers are attempting to structure new and innovative health care delivery systems to contain health care cost.

H.R. REP. NO. 104-496, pt. 1, at 84 (1996).

The same chilling effect would arise if pre-enforcement judicial review were unavailable to clarify the statute's scope; this effect implicates the due process rights of Pfizer and other regulated entities. *See Johnson v. United States*, 135 S. Ct. 2551, 2557 (2015) ("[T]he indeterminacy of the wide-ranging inquiry required by the [statute at issue] both denies fair notice to defendants and invites arbitrary enforcement by judges."); *Christopher v. SmithKline Beecham Corp.*, 132 S. Ct. 2156, 2168 (2012) ("It is one thing to expect regulated parties to conform their conduct to an agency's interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance or else be held liable when the agency announces its interpretations for the first time in an enforcement proceeding and demands deference."). This concern of fair notice also weighs in favor of a finding that an action like this one is ripe for review now, before industry members would be required to risk a violation of the AKS to test the government's view of the scope of that statute.

CONCLUSION

For the foregoing reasons, this action is both constitutionally and prudentially ripe, and this Court has jurisdiction to decide this action on the merits.

Dated: December 7, 2020

Respectfully submitted,

/s/ Jennifer C. Guest

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